

# Patient-reported Outcome Instruments in Lower Extremity Trauma: A Systematic Review of the Literature

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**Background:** Advances in fracture fixation and soft tissue coverage continue to improve the care of patients after limb-threatening lower extremity (LE) trauma. However, debate continues regarding which treatment option—reconstruction or amputation—is most appropriate. Many authors have attempted to quantify the patient experience in this treatment paradigm; however, they have not used patient-reported outcome (PRO) instruments specific to this population. Our aim was to identify and evaluate PRO instruments developed specifically for LE trauma, applicable to reconstruction and amputation, using established PRO instrument development and validation guidelines.

**Methods:** A multidisciplinary team used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses method to query PubMed, Medline Ovid, EMBASE, Cochrane, Medline Web of Science, and Psych Info databases from inception to November 2016. Publications were included that described the development and/or validation of a PRO instrument assessing satisfaction and/or quality of life in LE trauma, applicable to both amputation and reconstruction. Two authors independently reviewed each full-text citation.

**Results:** After removing duplicates, 6,290 abstracts were identified via the database query. Following a preliminary title and abstract screen, 657 full-text citations were reviewed. Of these references, none satisfied the previously established inclusion criteria.

**Conclusions:** No studies were identified that described a PRO instrument developed to assess outcomes in LE trauma patients applicable to both reconstruction and amputation. There is thus a need for a PRO instrument designed specifically for patients who have sustained limb-threatening LE trauma to guide treatment decisions. (*Plast Reconstr Surg Glob Open* 2019;7:e2218; doi: 10.1097/GOX.0000000000002218; Published online 3 May 2019.)

## INTRODUCTION

Severe lower extremity (LE) traumatic injuries are life-changing events. Treatment options include early

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amputation, limb reconstruction, or delayed amputation after reconstructive attempts; however, there is a no consensus regarding the best treatment modality.<sup>1-7</sup> Successful reconstruction may involve numerous operations with a high rate of complications and long-term disability.<sup>3,8</sup> However, amputation has its own limitations, including life-long reliance on a prosthesis for ambulation. In the setting of modern reconstructive microsurgery and orthopedic trauma care, the optimal treatment has not yet been established.

The impact of severe LE trauma is multidimensional. Traditional metrics including infection rates, postoperative complications, and pure functional assessments only capture a small portion of the experience borne by this patient population, neglecting outcomes such as return to work status, social integration, and substance abuse. A thorough assessment of the utility of amputation versus

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reconstruction must therefore be more comprehensive than the approach we have applied in the past to other surgical conditions, and therefore requires the development and application of a meaningful, appropriate patient-reported outcome (PRO) instrument.

PRO instruments are broadly categorized into 2 groups: generic and disease specific. Generic instruments evaluate concepts of interest (COI) across a broad range of patient populations, allowing for a general comparison of health and well-being. Disease-specific PRO instruments capture COI relevant to the disease process and allow an assessment of change within these COI domains.<sup>11</sup> Both types of PRO instruments are in contrast to ad hoc measures, which are a nonvalidated compilation of questions felt to be important by the research team and/or clinician.

Current PRO research in LE trauma has relied heavily upon generic measures, such as the SF-36 and Sickness Impact Profile. Disease-specific PRO instruments designed for populations other than LE trauma patients, such as the Prosthesis Evaluation Questionnaire (designed for amputees) and the Musculoskeletal (MSK) Tumor Society Scoring System (designed for MSK oncology) have also been used, along with ad hoc instruments.<sup>12-15</sup> Although these instruments may offer some insight into LE trauma patient experiences, none have been rigorously developed for, or validated in, the LE trauma population. Therefore, these instruments lack the content validity required to fully capture all COI relevant to these patients.

Given the stakes of LE trauma decision-making—the significant length of time, use of resources, and potential morbidity associated with salvage, and the permanence of amputation—a disease-specific, valid, reliable instrument allowing comparison between these treatment conditions is essential. To identify and evaluate available options, we conducted a systematic review of the literature. Our primary aim was to identify PRO instruments developed specifically for LE trauma patients, applicable to both reconstruction and amputation patient cohorts. Our secondary aim was to evaluate any identified instruments based on established guidelines for PRO instrument development and validation.<sup>16</sup>

## METHODS

### Search Strategy

A comprehensive search was designed with the assistance of a medical librarian using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines to identify PRO instruments assessing quality of life and/or satisfaction for patients with LE traumatic injuries, applicable to both patients undergoing reconstruction and/or amputation.<sup>17</sup> The search was conducted in PubMed, Medline Ovid, EMBASE, Cochrane, Medline Web of Science, and Psych Info, from inception to November 2016. Search terms were developed for LE trauma and outcome instruments, as listed in Table 1. The search terms were searched as text words and mapped to medical subject headings when applicable. Terms within each search category were combined with the Boolean

operator OR, and the 3 categories were combined with AND.

### Selection Criteria

Publications were included if they were published in English and if they described the development and/or validation of a PRO instrument designed to measure satisfaction and/or quality of life in LE trauma patients, applicable to both amputation and reconstruction cohorts. Conference abstracts, theses, letters to the editor, editorials, and review articles were excluded. Secondary searching, including a citation review of applicable publications, was performed to identify additional instruments. Corresponding authors were contacted to obtain additional information if necessary.

### Data Extraction

One author (L.R.M.) reviewed all titles and abstracts. All potentially applicable publications were reviewed as full-text by 2 authors (A.J.G. and L.R.M.). Any disagreements between A.J.G. and L.R.M. were resolved by consensus with the senior author (M.J.G.). All publications utilizing a PRO instrument that was not applicable to *both* amputation and reconstruction patients were excluded. Excluded citations were sorted into the following categories: ad hoc instruments, non-MSK PRO instruments, MSK PRO instruments not developed for LE trauma, MSK PRO instruments assessing functional outcomes only, PRO instruments specific to amputation patients only, LE PRO instruments specific to reconstruction only, and trauma PRO instruments not specific to the LE. Utilization frequencies of each PRO instrument in each category were also recorded.

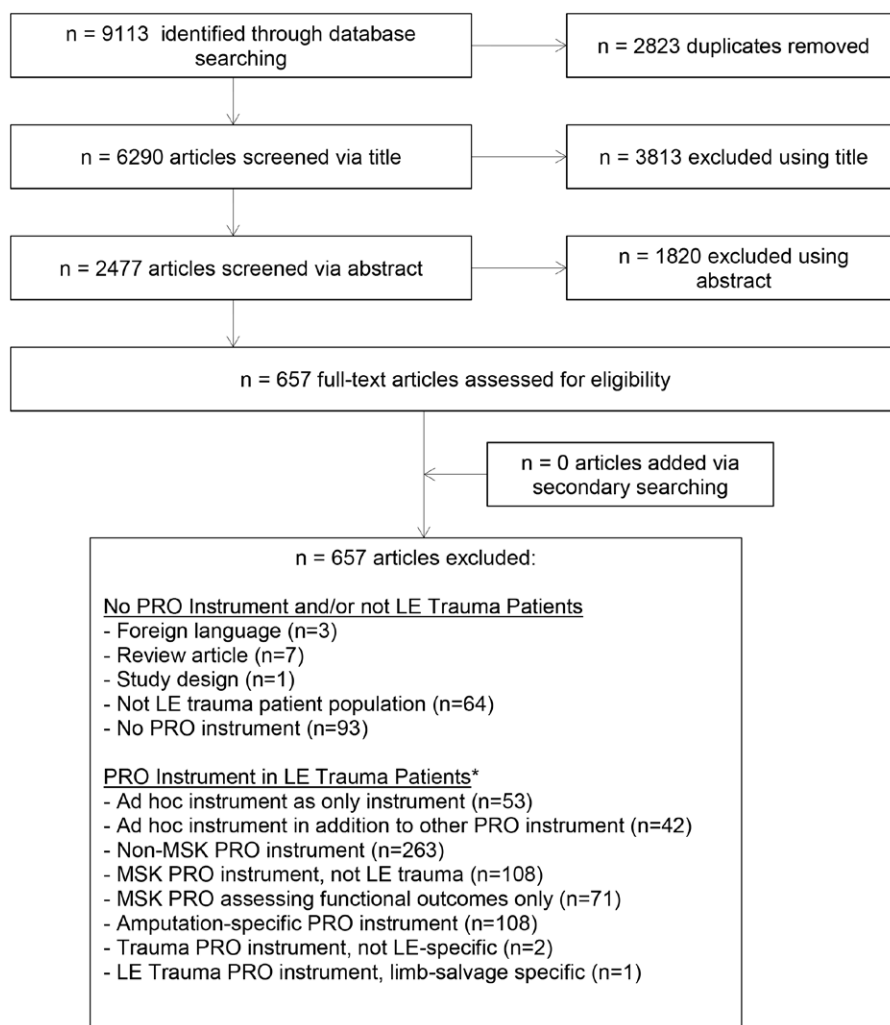
## RESULTS

The results of the electronic search are shown in Figure 1. There were 9,113 publications identified in the search, with 6,290 publications after removal of duplications. After the initial title and abstract screen, there were 657 articles remaining, all of which were reviewed in full text and assessed for eligibility. There were no articles meeting inclusion criteria; none described a PRO instrument assessing outcomes in LE trauma patients that were applicable to both reconstruction patients and amputation patients. There were no additional articles added via secondary searching. Table 2 reports the most frequently

**Table 1. Search Strategy**

Category	Terms
LE trauma	LE trauma, limb salvage, limb reconstruction, limb threaten*, amputation
Quality of life and/or patient satisfaction	Quality of life, health-related quality of life, functional status, function, well-being, health status, health status disparity, quality-adjusted life years, patient satisfaction
Outcome instrument	Patient-reported outcome, questionnaire, survey, instrument, measure, scale, assessment, treatment outcome, consumer satisfaction, psychometric*, data collection

\*LE, lower extremity.



LE = lower extremity, MSK = musculoskeletal

\* Publications with multiple instruments were counted in each associated group

**Fig. 1.** Flow diagram of systematic review. \*Publications with multiple instruments were counted in each associated group.

utilized PRO instruments that are used to assess outcomes in LE trauma patients. The majority of studies utilized multiple PRO measures, with a combination of ad hoc measures, generic PRO instruments, and disease-specific PRO instruments. These instruments were most commonly designed for nontrauma MSK injuries and/or disease processes. Table 3 lists the proposed domains for a novel PRO instrument for LE trauma patients, based on the topics covered in the instruments listed here and expert opinion.

## DISCUSSION

The decision to pursue reconstruction or amputation in the setting of limb-threatening LE trauma represents a significant challenge to both surgeons and patients. These injuries are often the result of high-energy mechanisms and patients present with extensive soft tissue loss, periosteal stripping, concomitant damage to neurovascular structures, and varying degrees of contamination.<sup>18</sup> Early

initiation of broad-spectrum antibiotic therapy, wound debridement, rigid fracture stabilization, and soft tissue coverage has revolutionized the treatment of these injuries and led to increased rates of limb salvage.<sup>2,19,20</sup> However, debate continues concerning who should undergo reconstruction versus amputation. Although each treatment group faces unique challenges, both groups have worse clinical and functional outcomes compared with the general population due to persistent wounds, multiple procedures, depression, pain, posttraumatic stress disorder, and, in the setting of amputees, difficulties with prostheses.<sup>21–25</sup>

The LE Assessment Project (LEAP) is the most comprehensive civilian study to date. This study attempted to determine whether amputated or salvaged patients had superior clinical, functional, and health-related quality of life outcomes using the Sickness Impact Profile.<sup>22,23,26</sup> This prospective observational trial of 601 patients enrolled from 1994 to 1997 found no difference in clinical and

**Table 2. Frequently Identified PRO Instruments Utilized for LE Trauma Patients**

Title	Year	Country	Specialty Population	Domains	No. Citations
<b>Non-MSK instruments</b>					
SF-36: Short Form 36 Health Survey <sup>23</sup>	1992	United States	General population	Vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, mental health	117
Sickness Impact Profile <sup>426</sup>	1975	United States	General population	Social interaction, ambulation and locomotion, sleep and rest, taking nutrition, usual daily work, household management, mobility and confinement, movement of the body, communication activity, leisure pastimes and recreation, intellectual functioning, interaction with family members, emotions, feelings and sensations, personal hygiene	34
SF-12: 12 Item Short Form Survey <sup>5,33</sup>	1996	United States	General population	Vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, mental health	18
HADS: Hospital Anxiety and Depression Scale <sup>6,34</sup>	1983	United Kingdom	General population	Anxiety, depression	13
EQ-5D: EuroQOL 5D <sup>7,35</sup>	1990	United Kingdom, The Netherlands, Sweden	General population	Mobility, self-care, usual activities, pain/discomfort, anxiety/depression, overall health status	12
WHOQOL: World Health Organization Quality of Life Questionnaire, BREF and 100 <sup>8,36</sup>	1995, 1998	Switzerland	General population, global use	Quality of life domains for: physical, psychological, social, environmental, level of independence,* spirituality, religion and personal beliefs,* overall	8
PROMIS: Patient-Reported Outcomes Measurement Information System <sup>9-11,37-39</sup>	2005	United States	General population	Physical functioning, fatigue, pain, emotional distress, social role participation	3
<b>MSK instruments, not LE trauma</b>					
American Orthopaedic Foot and Ankle Society Ankle-Hindfoot and Midfoot Rating Scales <sup>12,40</sup>	1994	United States	Ankle and foot pathology	Clinician and PROs for function, pain, alignment	32
SMFA: Short Musculoskeletal Function Assessment Questionnaire <sup>13,27</sup>	1999	United States	MSK disease	Dysfunction index, Bother index	13
ABC: Activities-specific Balance Confidence Scale <sup>14,41</sup>	1995	Canada	Elderly outpatients	Confidence in mobility and balance	12
WOMAC: Western Ontario <sup>42</sup> McMaster University Osteoarthritis Index <sup>4,15</sup>	1988	Canada	Osteoarthritis	Stiffness, pain, physical function	7
Musculoskeletal Tumor <sup>43</sup> Society Scoring System <sup>16</sup>	1993	United States	Limb salvage in MSK oncology	LE Scales: pain, function, emotional acceptance, supports, walking and gait	6
OPUS: Orthotics and Prosthetics Users' Survey <sup>17,44</sup>	2003	United States	Users of orthotics and prosthetics (upper and lower limbs)	Functional status, quality of life, satisfaction with prosthetics and orthotics	6

(Continued)

**Table 2. Continued**

Title	Year	Country	Specialty Population	Domains	No. Citations
<b>MSK physical function outcome instruments</b>					
LCI: Locomotor Capabilities Index <sup>†18,19,36,38</sup>	1998	Canada	LE amputees	Patient perceived capability to complete locomotor activities	21
LEFS: LE Functional Scale <sup>19</sup>	1999	United States, Canada	LE MSK diseases requiring physical therapy	Patient perceived difficulty with physical activities	16
Houghton Scale <sup>20,21,47</sup>	1992	United Kingdom	LE amputation prosthetic users	Use of prosthetic and mobility	14
<b>Amputation-specific instruments</b>					
PEQ: Prosthesis Evaluation Questionnaire <sup>12,22</sup>	1998	United States	LE amputation prosthetic users	Prosthetic function (usefulness, residual limb health, appearance, sounds), mobility (ambulation, transfers), psychosocial (perceived responses, frustration, social burden), well-being	37
TAPES: Trinity Amputation and Prosthesis Experience Scales <sup>23-25,50,51</sup>	2000	Ireland	LE amputation prosthetic users	Psychosocial adjustment (general, social, limitations), activity restriction (functional, social, athletic), prosthesis satisfaction (function, aesthetic, weight), pain (residual, phantom), general health, overall physical capabilities	21
Prosthetic Profile of the Amputee <sup>26,27,52,53</sup>	1994	Canada	LE amputees	Physical condition, prosthesis, prosthetic use, environment, leisure activities, general information	7
Q-TFA: Questionnaire for Persons With a Transfemoral Amputation <sup>28,54</sup>	2004	Sweden	Nonelderly transfemoral amputation prosthetic users	Prosthetic use, mobility, problems, global health	7
Amputee Body Image Scale <sup>29,49</sup>	2007	Ireland	LE amputation prosthetic users	Body image disturbances	6
<b>Limb salvage-specific instruments</b>					
Wulterkens Telephone Questionnaire <sup>35</sup>	2015	The Netherlands, France	Trauma, limb salvage	Function, daily life, psychology	1
Trauma, not LE specific Hannover Score for Polytrauma Outcome <sup>30,31,56,57</sup>	2001	Germany	Trauma	PRO†: General information, social relations, profession, status of pension, sports and hobbies, medications for orthopedic problems, medications in daily life, treatment during rehabilitation, financial, ability to remember hospital stay, daily problems, SF-12, questions from the musculoskeletal function assessment <sup>(32)</sup>	3

\*Included only in the WHOQOL-100, not the WHOQOL-BREF.

†A version of a scale within the Prosthetic Profile of the Amputee that is used independently.

‡Domains listed for PRO portion, also a clinician portion.



**Table 3. LE PRO Instrument Proposed Conceptual Framework**


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Appearance
Physical function
Psychosocial well-being
Sexual well-being
Employment
Prosthetics and orthotics
Satisfaction with experience
Satisfaction with outcome

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functional outcomes or with health-related quality of life, patient satisfaction with treatment, or rates of returning to work. Worse outcomes, based on the Sickness Impact Profile, were alternatively correlated with patient and environmental factors independent of treatment pathway, including lower socioeconomic status, non-white race, tobacco use, using the legal system for injury compensation, and low levels of self-efficacy.

The Military Extremity Trauma Amputation/Limb Salvage (METALS) study attempted to answer the same question in a military population.<sup>24</sup> A retrospective cohort study from 2003 to 2007 was performed on 324 service members who served in either Afghanistan or Iraq and who had suffered limb-threatening trauma to the LE. In addition to outcome measures for depression, posttraumatic stress disorder, chronic pain, and daily activities, general MSK PROs were evaluated with the Short Musculoskeletal Function Assessment (SMFA).<sup>27</sup> In contrast to the LEAP study, amputees had higher SMFA scores and engagement in vigorous sports in comparison to reconstruction patients. Amputation patients also had lower rates of posttraumatic stress disorder, although both groups had equivalent rates of employment and depression. These findings reflected the higher levels of intensive postinjury rehabilitation services and access to prostheses and support devices provided to the military amputees, in comparison with both civilian amputees and military reconstruction patients.

The LEAP and METALS studies have improved our understanding of treatment outcomes in high-energy LE trauma patients, but a major limitation to the above studies is the use of the Sickness Impact Profile, a generic PRO instrument, and the SMFA, a general MSK PRO instrument. These measures are appropriate tools to compare outcomes between LE trauma patients and either the general population or patients with various MSK diseases besides LE trauma. However, they do not have the sensitivity to evaluate LE trauma-specific COI that is critical to make comprehensive inferences about LE trauma treatment outcomes. Qualitative interviews of LE trauma patients have identified numerous COI that are of importance to this population, which are not captured in the above measures. Physical function and symptoms, appearance, psychosocial and sexual well-being, social support, impact on family, perceptions of recovery, coping, self-efficacy, medical decision-making, the impact on work and education, and impact on finances have all been identified as COI in qualitative research of LE trauma patients.<sup>28–30</sup>

Although many of these COI may be addressed in various other PRO instruments or ad hoc measures, no instru-

ment was found that comprehensively evaluates *all* COI relevant to LE trauma patients to allow for reproducible, rigorous comparisons between treatment outcomes. The most frequently observed paradigm was the use of a non-MSK-specific PRO instrument on patients with LE trauma (n = 266). It was also observed that authors often utilized an ad hoc instrument either alone (n = 61), or in addition to another PRO instrument (n = 44), in an attempt to describe the outcomes of their cohort. The frequency with which ad hoc instruments were employed further reinforces that there is a need for a metric capable of capturing and reporting severe LE trauma-relevant domains that are not adequately reflected in any of the currently available instruments.

With regards to study limitations, the results of this systematic review are dictated by the reliance upon the reviewed studies. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines were used to design our search query to reduce our risk of inadvertently omitting any studies that may be applicable to our hypothesis. However, missed relevant texts are possible. For those studies captured, the use of 2 separate reviewers reduced the possibility of selection bias from one reviewer.

## CONCLUSIONS

The results of this systematic review highlight the need for a rigorously developed, reliable, and well-validated outcome instrument to better understand those with limb-threatening LE trauma. This tool would allow for the collection of more specific outcomes to this population. Additionally, it would provide a better understanding of the domains that are most important to limb-threatened patients and focus our clinical efforts to provide a greater impact on their outcomes.

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